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Proposed Registration Decision PRD2012-19

DWB Pheromone Technical

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Overview

Proposed Registration Decision for DWB Pheromone Technical

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Isomate DWB, containing the technical grade active ingredient (TGAI) DWB Pheromone Technical, which contains the following four active compounds: (Z,Z)-3,13-octadecadien-1-yl acetate, (E,Z)-2,13-octadecadien-1-yl acetate, (Z,Z)-3,13-octadecadien-1-ol, and (E,Z)-2,13-octadecadien-1-ol. Isomate DWB is proposed for mating disruption of the dogwood borer (*Synathedon scitula*) on pome fruits, stone fruits, tree nut, highbush blueberry, and woody ornamental nursery crops.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of DWB Pheromone Technical and Isomate DWB.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on DWB Pheromone Technical, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on DWB Pheromone Technical, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is DWB Pheromone Technical?

DWB Pheromone Technical is a mixture of straight chain lepidopteran pheromones (SCLPs), containing 84.03% (Z,Z)-3,13-octadecadien-1-yl acetate, 5.75% (E,Z)-2,13-octadecadien-1-yl acetate, 1.58% (Z,Z)-3,13-octadecadien-1-ol, and 0.28% (E,Z)-2,13-octadecadien-1-ol. The combination of these four compounds constitutes the sex pheromone of the dogwood borer. In nature, this sex pheromone is produced by female moths and attracts male moths for mating.

Health Considerations

Can Approved Use of DWB Pheromone Technical Affect Human Health?

DWB Pheromone Technical, containing the SCLPs (Z,Z)-3,13-octadecadien-1-yl acetate, (E,Z)-2,13-octadecadien-1-yl acetate, (Z,Z)-3,13-octadecadien-1-ol, and (E,Z)-2,13-octadecadien-1-ol, is used to formulate the end-use product (EP) Isomate DWB, which is unlikely to affect human health when it is used according to label directions.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Exposure to DWB Pheromone Technical may occur when handling Isomate DWB, which has a proposed commercial use as a mating disruptor of the dogwood borer. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

DWB Pheromone Technical is of low acute toxicity via the oral, dermal and inhalation routes. It is non to minimally irritating to eyes, mildly irritating to skin, and is not considered a dermal sensitizer.

Dermal exposure is possible for workers handling Isomate DWB during placement of the dispensers. The precautionary measures including personal protective equipment (PPE) and cautionary statements alerting users to the potential for skin irritation are required on the technical grade active ingredient and end-use product labels to mitigate such exposure concerns. The potential for bystander exposure is expected to be minimal.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The use of Isomate DWB formulated with DWB Pheromone Technical is not expected to result in unacceptable dietary risks when the product is used according to label directions. In addition, as the active ingredients are enclosed in a polymeric dispenser, and the dispensers will be attached to trees, exposure to the technical grade active ingredient in drinking water is not expected to occur. The PMRA has also determined that a maximum residue limit (MRL) is not required for Isomate DWB.

Occupational Risks From Handling Isomate DWB

Occupational risks are not of concern when Isomate DWB is used according to label directions, which include protective measures.

Occupational exposure to individuals handling Isomate DWB is not expected to result in unacceptable risk when the product is used according to label directions.

Precautionary and hygiene statements on the label (for example, wearing of personal protective equipment) are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When DWB Pheromone Technical Is Introduced Into the Environment?

DWB Pheromone Technical is released into the environment through passive vaporization into air from Isomate DWB fixed dispensers. The SCLP components of DWB Pheromone Technical are a group of chemicals that are naturally-based and are well known to break down rapidly in the environment. Through this use pattern, and because of the inherent nature of the chemicals, limited environmental exposure is expected.

Value Considerations

What Is the Value of Isomate DWB?

Isomate DWB has value in disrupting the mating of dogwood borers, thus reducing the production of larvae that would otherwise damage woody plants, including fruit and nut trees, highbush blueberries, and various ornamentals.

Application of Isomate DWB slow-release dispensers containing DWB Pheromone Technical in fruit or nut orchards, highbush blueberry fields, or nurseries for woody ornamentals produces numerous artificial sources of sex pheromone. This interferes with the ability of male moths to find females for mating and unmated females cannot lay fertile eggs; therefore, the next generation of larvae is reduced, limiting the damage the larvae would otherwise cause. Dogwood borer larvae tunnel under the bark of a wide variety of tree species and other woody plants, seriously weakening them and killing smaller trees or plants by girdling.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Isomate DWB to address the potential risks identified in this assessment are as follows.

Human Health

The signal words 'CAUTION – SKIN IRRITANT' and the statements 'May irritate skin' and 'Avoid contact with skin' are required on the principal and secondary display panels, respectively.

The personal protective equipment for all users includes chemical-resistant gloves and eye protection.

Environment

No environmentally-related mitigative measures are required.

Next Steps

Before making a final registration decision on DWB Pheromone Technical and Isomate DWB, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on DWB Pheromone Technical (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

DWB Pheromone Technical

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

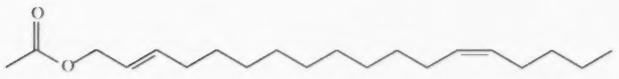
Active substances	1. (Z,Z)-3,13-octadecadien-1-yl acetate 2. (E,Z)-2,13-octadecadien-1-yl acetate 3. (Z,Z)-3,13-octadecadien-1-ol 4. (E,Z)-2,13-octadecadien-1-ol
Function	Pheromone
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	1. (Z,Z)-3,13-octadecadien-1-yl acetate 2. (E,Z)-2,13-octadecadien-1-yl acetate 3. (Z,Z)-3,13-octadecadien-1-ol 4. (E,Z)-2,13-octadecadien-1-ol
2. Chemical Abstracts Service (CAS)	1. 3,13-octadecadien-1-ol, 1-yl acetate, (3Z, 13Z)- 2. 2,13-octadecadien-1-ol, 1-yl acetate, (2E, 13Z)- 3. 3,13-octadecadien-1-ol, (3Z,13Z) 4. 2,13-octadecadien-1-ol, (2E,13Z)
CAS numbers	1. 53120-27-7 2. 86252-65-5 3. 66410-24-0 4. 123551-47-3
Molecular formulas	1 and 2. $C_{20}H_{36}O_2$ 3 and 4. $C_{18}H_{34}O$
Molecular weights	1 and 2. 308 3 and 4. 266

Structural formulas

1.

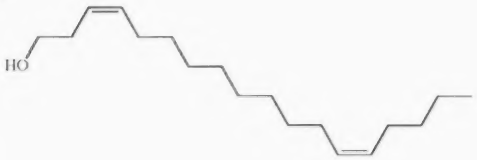
(Z,Z)-3,13-Octadecadien-1-yl acetate (PTZ)

2.



(E,Z)-2,13-Octadecadien-1-yl acetate (EOA)

3.



(Z,Z)-3,13-Octadecadien-1-ol (ZTO)

4.

(E,Z)-2,13-Octadecadien-1-ol (EZO)

Purity of the active ingredients

1. (Z,Z)-3,13-octadecadien-1-yl acetate.....84.03%
2. (E,Z)-2,13-octadecadien-1-yl acetate.....5.75%
3. (Z,Z)-3,13-octadecadien-1-ol.....1.58%
4. (E,Z)-2,13-octadecadien-1-ol.....0.28%

1.2 Physical and Chemical Properties of the Active Ingredient and End-use Product

Technical Product—DWB Pheromone Technical

Property	Result
Colour and physical state	Light yellow liquid
Odour	Mild waxy and sweet
Melting range	N/A
Boiling range	1. 175–180°C / 267 Pa 2. 19–203°C / 66 Pa 3. 180–193°C / 66 Pa 4. 180–293°C / 66 Pa
Specific gravity	0.874–0.885 at 20°C

Property	Result
Vapour pressure at 20°C	1. 2.4 mPa 2. 0.2–0.5 mPa (estimated) 3. 0.5–0.9 mPa (estimated) 4. 0.5–0.9 mPa (estimated)
Ultraviolet (UV)-visible spectrum	1. No absorbance at $\lambda > 400$ nm 2, 3 and 4. Not required as no hazard to biota was noted
Solubility in water at 20°C	1. not soluble 2. <0.02 mg/L 3. <0.03 mg/L 4. <0.03 mg/L
Solubility in organic solvents	Soluble in all common organic solvents
n-Octanol–water partition coefficient (log K_{ow})	1. >3 2. >5 3. >4 4. >4
Dissociation constant (pK_a)	None of the active ingredients contain a dissociable moiety
Stability (temperature, metal)	Stable under normal conditions, but gradually isomerizes and polymerizes under exposure to sunlight.

End-use Product—Isomate DWB

Property	Result
Colour	Colourless or light yellow
Odour	Mild waxy and sweet
Physical state	Liquid
Formulation type	Slow-release generator
Guarantee	(Z,Z)-3,13-octadecadien-1-yl acetate.....79.84% (E,Z)-2,13-octadecadien-1-yl acetate.....5.46% (Z,Z)-3,13-octadecadien-1-ol.....1.50% (E,Z)-2,13-octadecadien-1-ol.....0.27%
Container material and description	HDPE dispenser tube containing pheromone; 500 dispenser units per package
Specific gravity	0.889 at 20°C
pH of 1% dispersion in water	3.57
Oxidizing or reducing action	None

Property	Result
Storage stability	When stored for 12 months at room temperature and 5°C, losses of 5.48% and 1.55% were observed. The label storage instructions indicate that the unopened package must be stored at a temperature below 4°C in a dry location.
Corrosion characteristics	Not corrosive
Explodability	Not explosive

1.3 Directions for Use

Isomate DWB is for use in pome fruit, stone fruit, and tree nut orchards, highbush blueberry fields, and nurseries for woody ornamental plants to disrupt mating of the dogwood borer (*Synanthedon scitula*). Individual Isomate DWB dispensers are manually installed on lateral branches within the plant canopy at overall rates of 250–375 dispensers (15.8–23.7 g pheromone) per hectare. The low rate may be used when pest pressure is low or where mating disruption has been practiced for a number of years, the high rate is recommended when pest pressure is high or in the initial year of treatment, and the application rate should be doubled around the borders of the treatment area, but only to a maximum of 500 dispensers per hectare. Application timing is in the spring, prior to adult moth emergence.

1.4 Mode of Action

The precise mode of action of mating disruption is not completely understood. For example, it may be behavioural, with males being attracted to pheromone dispensers rather than to females; it may be physiological, with the insect nervous system becoming habituated and ceasing to respond to the continuous presence of pheromone in the atmosphere; or it may involve more than one mechanism. In any case, the end result is that males fail to find females for mating and therefore the females cannot reproduce. If enough females fail to reproduce, the subsequent larval population may be low enough that damage is maintained below economic thresholds.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredients and the impurities in DWB Pheromone Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredients in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for DWB Pheromone Technical consisting of waiver rationales and published scientific literature was conducted. The scientific quality of the data is acceptable and the database is sufficiently complete to define the majority of the toxic effects that may result from exposure resulting from the intended use of this pest control product.

The toxicology of SCLPs has been well-characterized as being of low toxicity, and it is expected that most SCLP-containing products will pose low potential risk to human health. SCLPs are long-chain fatty acids that are metabolized either by β-oxidation, or by conjugation with glucuronide and subsequent excretion by the kidneys. The USEPA, the PMRA, and the European Union regulatory authorities have received no reports of adverse effects to human health or the environment associated with SCLP-containing EPs.

A data waiver rationale was accepted to bridge the acute toxicity studies submitted in support of (Z,Z)-3,13-octadecadien-1-yl acetate and another SCLP in the previously registered Peachtree Borer Pheromone Technical (Registration number 27140) for the toxicology data requirements for DWB Pheromone Technical and Isomate DWB. Peachtree Borer Pheromone Technical was of low acute toxicity via the oral, dermal and inhalation routes, was minimally irritating to the eyes, and mildly irritating to the skin. It was not considered to be a dermal sensitizer.

A data waiver rationale was also accepted for bacterial reverse mutation assay, in vitro mammalian cell assay, and mammalian bone marrow chromosome aberration assay based on a rationale of low potential for exposure from the proposed use pattern, and the absence of mutagenicity of Peachtree Borer Pheromone Technical in an Ames assay with or without metabolic activation.

3.2 Food Residue Exposure Assessment

3.2.1 Food and Drinking Water

Isomate DWB, consists of two parallel polyethylene tubes, one of which is filled with a wire to allow the dispenser to be twisted around the tree branch (not contacting the food/fruit), while the other tube is impregnated with the pheromone formulation. The active ingredient is slowly released from the dispenser, resulting in a low concentration of pheromone in the atmosphere. The release rate for Isomate DWB (15.8–31.65 g pheromone/ha/year) is slightly higher than the release rate for the previously registered SCLP-containing Isomate-P Pheromone (9.45–23.63 g pheromone/ha/year) (Registration number 27141) and lower than the release rate for Isomate-PTB Dual (42.09–75.76 g pheromone/ha/year) (Registration number 30042). Therefore, the use of Isomate DWB formulated with DWB Pheromone Technical is not expected to result in unacceptable dietary risks when the product is used according to label directions. In addition, as the active ingredients are enclosed in a polymeric dispenser, and the dispenser will be attached to trees, exposure to the technical grade active ingredient in drinking water is not expected to occur.

3.2.2 Maximum Residue Limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

As Isomate DWB, consists of a solid-matrix dispenser which is not in direct contact with a food crop, and food residues from airborne transfer of SCLPs were not reported, the establishment of an MRL is not required (Regulatory Proposal PRO2002-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*).

3.3 Occupational and Bystander Risk Assessment

3.3.1 Use Description/Exposure Scenario

Isomate DWB consists of two parallel polyethylene tubes, one of which is filled with a wire to allow the dispenser to be twisted around the tree branch, while the other tube is impregnated with the pheromone formulation. The active ingredient is slowly released from the dispenser, resulting in a low concentration of pheromone in the atmosphere. Each dispenser contains 63.3 mg of pheromone. The end-use product label states a minimum application rate of 250 dispensers per hectare, and a maximum rate of 500 dispensers per hectare. This would result in a release of 15.8–31.65 g pheromone/ha/year, which is comparable to the release rates for the previously registered SCLPs as noted above (see Section 3.2.1).

3.3.2 Applicator Exposure and Risk Assessment

Occupational exposure to the pheromone formulation is expected to be mainly by the dermal route which is possible during handling and attachment of the dispensers on the trees. Precautionary statements on the end-use product label require the user to wear personal protective equipment including chemical resistant gloves and eye protection, and instruct users to avoid contact with skin, eyes and clothing, and to wash hands with soap and water after use. Due to the low toxicity of SCLPs, inhalation exposure is not expected to be a concern. Occupational exposure to Isomate DWB is therefore expected to be minimal when workers follow label instructions.

3.3.3 Bystander Exposure and Risk Assessment

Bystander exposure is expected to be negligible as the commercial application of Isomate DWB is expected to involve authorized personnel only who would be expected to follow label instructions, including personal protective equipment, precautionary statements, and hygiene statements.

3.3.4 Post-Application Exposure

Exposure of workers performing post-application activities that involve handling the dispensers is expected to be minimal, provided the label instructions, which include personal protective equipment, precautionary statements, and hygiene statements, are observed. Postapplication exposure of individuals performing tasks which do not involve handling the dispensers, such as pruning or harvesting, will not require any personal protective equipment, or additional statements regarding precautionary and/or hygiene information on the label.

3.4 Incident Reports Related to Human and Animal Health

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. No health-related incident reports for products containing (Z,Z)-3,13-octadecadien-1-yl acetate, (E,Z)-2,13-octadecadien-1-yl acetate, (Z,Z)-3,13-octadecadien-1-ol, and (E,Z)-2,13-octadecadien-1-ol have been received by PMRA. Incidents from the United States were searched and reviewed for products containing (Z,Z)-3,13-octadecadien-1-yl acetate, (E,Z)-2,13-octadecadien-1-yl acetate, (Z,Z)-3,13-octadecadien-1-ol, and (E,Z)-2,13-octadecadien-1-ol for use as pesticides. As of April 23, 2012, there were no health-related incident reports reported by the USEPA or the California Department of Pesticide Regulation (CalDPR) for EPs containing these active ingredients.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

SCLPs consist of unbranched aliphatic compounds. Breakdown in the environment is rapid, primarily through oxidative processes with enzymes found ubiquitously in nature. Therefore, when DWB Pheromone Technical is released into the environment, the active ingredients are expected to degrade rapidly. The technical grade active ingredient is released through volatilization. The chemical is expected to remain as a vapour and degrade rapidly, and is not expected to partition to water, soil, or to non-target organism food materials.

4.2 Environmental Risk Characterization

The risk assessment for DWB Pheromone Technical is qualitative.

4.3 Effects on Non-Target Species

As per Regulatory Proposal PRO2002-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*, no environmental toxicity data are required for SCLP technical grade active ingredients and end-use products if release is through a fixed dispenser.

Based on the application methods (passive release from fixed dispensers into air), expected rapid breakdown, and limited partitioning potential to water or soil, exposure to non-target aquatic and terrestrial organisms in crop areas will be low. Therefore, the use of the technical grade active ingredient in the product does not pose a concern to non-target organisms.

5.0 Value

5.1 Description of Pest Problem

Dogwood borer has been reported to attack a wide variety of tree species and even woody shrubs such as blueberry. Larvae tunnel under the bark, weakening the trees and killing branches and smaller trees or shrubs by girdling. Dogwood borer is a sporadic pest but of increasing importance to apple growers because of a preference for attacking the "burr knots" (dense aggregations of root initials) that form near the grafting point on common dwarfing rootstocks which have become prevalent in commercial apple production during the past few decades.

5.2 Effectiveness Against Pests

Efficacy data were evaluated from two field trials, one five-year trial (2005–2009) in Pennsylvania and one two-year trial (2008–2009) in Ontario, both conducted in apple orchards. Both trials clearly showed that Isomate DWB disrupts the attraction of dogwood borer to pheromone-baited traps, suggesting the ability of males to locate females may be similarly disrupted. Declines in larval infestation further suggested a reduction in reproductive success of the pest.

5.2.1 Acceptable Efficacy Claims

The submitted efficacy data and available information support the use of Isomate DWB for mating disruption of dogwood borer in pome fruit, stone fruit, tree nut, highbush blueberry, and woody ornamental nursery crops by application of 250-375 dispensers per hectare, and up to 500 dispensers per hectare around the borders of treatment areas, prior to adult moth emergence in the spring (see Appendix I, Table 2 for complete details).

5.3 Phytotoxicity to Host Plants

Phytotoxicity to host plants was not assessed; however, phytotoxicity is not expected because the active ingredients occur naturally in the environment and are not applied directly to the host plants but are released by volatilization from the dispensers.

5.4 Economics

No economic analysis was conducted for this product evaluation.

5.5 Sustainability

5.5.1 Survey of Alternatives

The only commercial alternative for control of dogwood borer in Canada is permethrin, with three EPs registered for use on apple by application directly to the tree trunks in a tank mix with oil.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Isomate DWB is compatible with current management practices and is particularly well suited to integrated pest management. Due to the non-toxic and species-specific nature of pheromones, they have no direct adverse effects on other pest management strategies, such as the use of beneficial parasites and predators.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Development of resistance to mating disruption has not been clearly demonstrated and the development of resistance to pheromone-based pest management strategies in general is considered unlikely.

5.5.4 Contribution to Risk Reduction and Sustainability

Due to the non-toxic and species-specific mode of action of the active ingredients, Isomate DWB should have no direct adverse effects on non-target organisms and may reduce the need for application of conventional insecticides.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, DWB Pheromone Technical was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

DWB Pheromone Technical does not meet the Track 1 criteria and will not form any transformation products which meet the Track 1 criteria. DWB Pheromone Technical contains naturally-based substances and is not expected to be persistent or bioaccumulative in the environment

7.0 Summary

7.1 Human Health and Safety

The available information on SCLPs is adequate to qualitatively identify the toxicological hazards that may result from the proposed use of Isomate DWB. DWB Pheromone Technical is likely to be of low acute toxicity via the oral, dermal, and inhalation routes. It is minimally irritating to the eyes, mildly irritating to the skin, is not a dermal sensitizer, and is considered to be non-mutagenic.

Occupational exposure to Isomate DWB is expected to be minimal if the precautionary and hygiene statements and recommended personal protective equipment on the product label, which are intended to minimize worker exposure, are observed. Bystander exposure is likely to be negligible. Postapplication exposure can be minimized by following the precautionary statements on the label.

Dietary exposure to DWB Pheromone Technical from the use of Isomate DWB is not expected to result in unacceptable dietary risks when the product is used according to label instructions. The Agency did not establish a maximum residue limit (MRL) for DWB Pheromone Technical.

7.2 Environmental Risk

The active ingredients are SCLPs, a group of chemicals that are naturally-based and are well known to break down rapidly in the environment. The technical grade active ingredient is released into the environment through passive vaporization into air from fixed dispensers. Partitioning to water or soil is not expected to occur, and exposure to non-target aquatic and terrestrial organisms in crop areas will be low and does not pose a concern. Therefore, risk to the environment is expected to be minimal with the use of this DWB Pheromone Technical in the Isomate DWB.

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[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

7.3 Value

Isomate DWB has value in disrupting mating of the dogwood borer, providing a low-risk alternative for reducing production of larvae that would otherwise damage apple and other orchard and nursery crops.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of DWB Pheromone Technical and Isomate DWB containing DWB Pheromone Technical, to control dogwood borer (*Synathedon scitula*) in pome fruits, stone fruits, tree nut, highbush blueberry, and woody ornamental nursery crops.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

λ	wavelength
bw	body weight
CAS	Chemical Abstracts Service
EP	End-use product
g	gram
ha	hectare(s)
HDPE	high-density polyethylene
kg	kilogram
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
mg	milligram
MIS	Maximum mean irritation score
MIIS	Maximum individual irritation score
mL	millilitre
mPa	Megapascals
MRL	maximum residue limit
N/A	Not Applicable
PA	Pascals
PMRA	Pest Management Regulatory Agency
SCLP	straight chain lepidopteran pheromone
TGAI	Technical grade active ingedient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Tables and Figures

Table 1 **Summary of acute toxicity, irritative effects, sensitization and mutagenicity information for Peachtree Borer Pheromone Technical [89.3% w/w (Z,Z)-3,13-octadecadien-1-yl acetate]**

STUDY	SPECIES/STRAIN AND DOSES	RESULT	TARGET ORGAN / SIGNIFICANT EFFECTS / COMMENTS	REFERENCE (PMRA NUMBER)
Oral toxicity (Limit test) Exposure by gavage	Rat – Sprague Dawley (5/sex)	LD_{50} (♀) > 5000 mg/kg bw LD_{50} (♂) > 5000 mg/kg bw **Low acute toxicity.**	No mortality occurred.	1042180
Dermal	Rat – Sprague Dawley (5/sex)	LD_{50} (♀) > 2000 mg/kg bw LD_{50} (♂) > 2000 mg/kg bw **Low acute toxicity.**	No mortality occurred.	1042181
Inhalation Nose-only exposure chamber	Rat – Sprague Dawley (5/sex)	LC_{50} (♀) > 5.32 mg/L LC_{50} (♂) > 5.32 mg/L **Low acute toxicity.**	No mortality occurred.	1042082
Eye Irritation Draize method	Rabbit – New Zealand White (6 males) Dose: 0.1 mL of test substance. Eyes were left unwashed.	MIS[a] = 6.67/110 (at 1 hour) **Non to minimally irritating.**	Ocular irritation cleared by 48 hours.	1042183
Dermal Irritation Draize method	Rabbit – New Zealand White (3/sex) Dose: 0.5 mL of test substance applied for 4 hours.	MIIS[b] = 3/8. **Mildly irritating.**	Erythema cleared by Day 7, edema cleared by 48 hours. Thickening and epidermal scaling observed.	1042184
Dermal Sensitization	Guinea pigs – Hartley albino	Negative results. Not a dermal sensitizer.	No positive reactions were observed following challenge	1042185

STUDY	SPECIES/STRAIN AND DOSES	RESULT	TARGET ORGAN / SIGNIFICANT EFFECTS / COMMENTS	REFERENCE (PMRA NUMBER)
Buehler method	Test group = 5/sex Vehicle control group = 2/sex		in any test or negative control animals.	
Bacterial reverse mutation assay Plate incorporation test	*Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538.	Non-mutagenic.	No biologically relevant increases in revertant colony numbers of any of the tester strains were observed at any concentration, in the presence or absence of metabolic activation.	1042172

[a]MIS: Maximum mean irritation score
[b]MIIS: Maximum individual irritation score

Table 2 Use Claims Proposed by Applicant and Whether Acceptable or Unsupported

Use Claim	Proposed by Applicant	PMRA Supported
Crops	Apples and other pome fruits; plums, cherries and other stone fruits; pecans and other tree nut crops; blueberries and other berry crops and dogwood, crabapple, oak, birch, mountain ash, willow, pine and other ornamental nursery crops.	Pome fruits (apple, crabapple, mayhaw, pears, quinces), stone fruits (plums, cherries, apricot, capulin, chokecherry, nectarine, peach, plumcot, sloe), tree nuts (pecan, almond, beech nut, butternut, chestnut, chinquapin, filbert, hickory nut, walnut), highbush blueberry and woody ornamental nursery crops (including dogwood, birch, crabapple, elm, flowering cherries, mountain ash, oak, willow, pine).

Use Claim	Proposed by Applicant	PMRA Supported
Pests	Dogwood borer *(Synanthedon scitula)*.	Accepted as proposed.
Application Rate	Minimum of 250 dispensers per hectare (100 dispensers per acre) for low populations areas and where dogwood borer mating disruption has been practiced for a number of years. Maximum of 500 dispensers per hectare (200 dispensers per acre). Rate of 375 dispensers per hectare (150 dispensers per acre) is recommended for the initial treatment year and for high populations, including around borders of treatment area.	Minimum of 250 dispensers per hectare (100 dispensers per acre) for low population areas and where dogwood borer mating disruption has been practiced for a number of years. Rate of 375 dispensers per hectare (150 dispensers per acre) is recommended for the initial treatment year and for high populations. Double the rate, up to a maximum of 500 dispensers per hectare (200 dispensers per acre), around borders of treatment area.
Application Timing	Apply in the spring before the end of May. It is important to apply prior to dogwood borer adult emergence. Consult a local extension specialist or Pacific Biocontrol representative for proper timing or estimated dispenser longevity in your area.	Accepted as proposed.
Application Method	Dispensers should be placed on lateral branches at chest height within the tree.	Dispensers should be placed on lateral branches at chest height within the tree canopy.
Notes	ISOMATE DWB reduces mating of target pests. Immigration of mated female moths of these species from adjacent orchards will reduce the level of control. Manage by: a. Treatment of external sources of infestation with ISOMATE DWB. b. Treatment of external sources of infestation with a registered insecticide. c. Treatment of pheromone treated orchard with a registered insecticide Areawide application is most effective. Supplementary applications of registered insecticides are advised when ISOMATE DWB is used in orchards with high pest populations. All pests must be monitored so that timely intervention with registered insecticides is possible.	ISOMATE DWB reduces mating of the target pest. Immigration of mated female moths of this species from adjacent orchards or nurseries will reduce the level of control. Manage by: Accepted as proposed.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

Technical Grade Active Ingredient

PMRA Number	Reference
1925919	2010, Part 2, Product Chemistry for Registration of a TGAI, DACO: 2.0,2.14.6 CBI
2142095	2011, Part 2, Product Chemistry for Registration of a TGAI, DACO: 2.0,2.1,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3,2.14,2.14.1,2.14.11,2.14.14,2.14.2,2.14.3,2.14.5,2.14.7,2.14.8,2.14.9,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2142109	2011, CBI Reference to Parent Document, Part 2, Product Chemistry for Registration of a TGAI, DACO: 2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3 CBI
2186312	2012, Part 2, Product Chemistry for Registration of a TGAI, DACO: 2.13.3
2142209	2011, Part 3, Product Chemistry for Registration of an EP, DACO: 3.0,3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.2.1,3.2.2,3.3.1,3.4,3.4.1,3.5,3.5.1,3.5.10,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.9 CBI
2142210	2011, CBI Reference to Parent Document, Part 3, Product Chemistry for Registration of an EP, DACO: 3.0,3.1.2,3.2.1,3.2.2,3.3.1,3.4,3.4.1 CBI
2186304	2012, Part 3, Product Chemistry for Registration of an EP, DACO: 3.5.10

2.0 Impact on Human and Animal Health

PMRA Number	Reference
2142148	2011. Part 4, Acute Toxicology Studies for Registration of a TGAI (DWB Pheromone Technical). Unpublished, DACOs 4.1 – 4.2.6, 4.5.4, 4.5.5, 4.5.6.
2142252	2011. Part 4, Acute Toxicology Studies for Registration of an EP (Isomate-PTB Dual). Unpublished, DACOs 4.6.1 – 4.6.6.
2142261	2011. Part 5, Exposure (Occupational and Bystander) for Registration of an EP (Isomate DWB). Unpublished, DACO 5.1, 5.2

3.0 Value

PMRA Number **Reference**

2142189 2011. Part 10, Value for Registration of an EP: Isomate DWB, Volume 1. DACO 10.1-10.5

2142196 2011. Part 10, Value for Registration of an EP: Isomate DWB, Volume 2. DACO 10.1-10.5

B. Additional Information Considered

i) Published Information

1.0 Impact on Human and Animal Health

PRDD2004-03: Isomate-P Pheromone for use in Orchards for Mating Disruption of the Peach Tree Borer.

USEPA Biopesticides Registration Action Document: (E,Z)-2,13-Octadecadien-1-yl Acetate, PC Code 117242, and (E,Z)-2,13-Octadecadien-1-ol, PC Code 117244. August 23, 2011.

US Code of Federal Regulations 40: Protection of Environment, Part 180 – Tolerances and Exemptions for Pesticide Chemical Residues in Food, Subpart D – Exemptions from Tolerances 180.1153 Lepidopteran pheromones; exemption from the requirement of a tolerance.